TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
VENTRIA BIOSCIENCE MEETING)
)

Pages: 1 through 9

Place: College Park, Maryland

Date: February 25, 2004

HERITAGE REPORTING CORPORATION
Official Reporters
1220 L Street, N.W., Suite 600
Washington, D.C. 20005-4018
(202) 628-4888
hrc@concentric.net

IN THE UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
VENTRIA BIOSCIENCE MEETING)
)

Room 1A-001
Federal Drug Administration
5100 Paint Branch Parkway
College Park, Maryland

Wednesday,
February 25, 2004

The parties met, pursuant to the notice, at 10:07 a.m.

BEFORE: MS. CINDY SMITH

APPEARANCES:

For United States Department of Agriculture, Animal Plant Health Inspection Service, Biotechnology Regulatory Services:

REBECCA BECH, Associate Deputy Administrator
SUSAN KOEHLER
JOHN TURNER
NEIL HOFFMAN

For Ventria Bioscience:

STACEY R. ROBERTS, Director of Field Production

P R O C E E D I N G S

(10:07 a.m.)

MS. SMITH: We welcome you here for our next session. What I would like to suggest that we do, just in the interest of time, since you were just here in the last session as a member of BIO, I think we will omit our introductory remarks that we have been making, since you had the opportunity to just hear them. You probably don't need me to walk through them again.

So what we'll do is we'll just open up the discussion to any kind of a statement that you want to share, or any kind of questions that you want to ask. This is your time.

MS. ROBERTS: Thank you very much.

MS. SMITH: You're welcome.

MS. ROBERTS: I should say that my name is Stacey Roberts. I am with Ventria Bioscience, and that we were very well served by BIO's comments and questions, and APHIS's response.

I'm here on behalf of the leadership and staff of Ventria Bioscience, and we would like to extend our thanks to the Deputy Administrator, Cindy Smith, as well as t Dr. Susan Koehler and the biotechnologists at BRS. We wish to thank you all for your past guidance, as well as for the opportunity to participate here today.

Ventria Bioscience is a biotechnology company specializing in the production of pharmaceuticals and self-pollinated crops. We have been conducting field trials in California under permit since 1997, and we are approaching the commercialization of two of our proteins.

The resolution of issues raised in the Federal Register Notice of January 23 are extremely important to the continued ultimate success of our developing industry.

We have a few very brief comments related specifically to our company and the Federal Register Notice.

First, Ventria encourages, as BIO does, the USDA and APHIS to quickly set appropriate adventitious presence levels, when both the host plant and molecule of interest are well understood, and have been evaluated for risk and hazard based on current scientific principles.

In particular, Ventria supports so-called plant-made pharmaceuticals, or PMP production, in food crops, because it greatly improves the development, affordability, and global availability of life-enhancing and life-saving remedies.

Examples for which PMP production and field crops are ideal include products for the inclusion in oral rehydration solution, to treat infant diarrhea, one of the leading causes of childhood death, according to the World Health Organization. Products that improve iron balance in

women, adolescents, and children. This is in view of the fact that iron deficiency afflicts nearly 67 percent of the world population. And for obesity treatments delivered orally, for conditions which are largely preventable.

These are all examples of PMPs requiring easily deliverable large quantities of material. Without the ability to utilize food crops as a host, these, and many other life-enhancing and lifesaving remedies, would simply not be feasible.

Furthermore, extensive widespread agricultural understanding of food plants, including their genetics, agronomics, environmental impacts, and composition allow us to understand, manage, and mitigate potential risk to both the environment and end users.

We encourage USDA to consider regulations based on sound science, using a multi-tiered risk categorization, and assigned on a case-by-case basis, using, in part, the following criteria.

The impact of the biology of the host plant should be carefully evaluated based on outcrossing risk.

Self-pollinating hosts in male sterility are available technologies that can greatly reduce the risk of outcrossing.

The impact of the host plant and genes should be evaluated on how the molecule of interest and selectable

markers are expressed in the plant.

Specific technologies to be encouraged within the regulatory framework include expression of the molecule of interest in the harvestable organ, leaving little active material in the field. We would further suggest that preventing the expression of a selectable marker or removal of the selectable marker are viable strategies for reducing environmental impact.

In addition, the impact of the gene of interest can be evaluated on host plant survival. And if there is no selective advantage, this should again be included.

Finally, we hope that a tiered flexible system will help us set adventitious presence for certain food crop PMPs.

MS. SMITH: Okay, thank you. Very good comments.

MS. ROBERTS: If you have any comments or questions for me, please.

MS. SMITH: Do we have any questions?

MS. KOEHLER: I was wondering if you had an opinion on the question on --, where APHIS is considering establishing a new mechanism involving -- sorry, my name is Susan Koehler -- involving the states and the producer for commercial production of plants not intended for food or feed in cases where the producer would prefer to develop and extract pharmaceutical and industrial compounds under

confinement conditions, with governmental oversight, rather than the approval process for unconfined release, which would be the characteristics of this mechanism. To what extent should this mechanism be employed for commercial production of plants not intended for food or feed, what environmental consideration should influence the development of this mechanism?

And I was thinking maybe you could comment on the California Rice Commission, and your experience with them in relationship to this question.

MS. ROBERTS: We are working very closely with the California Rice Commission to develop a set of protocols which will keep all of our rice out of all of their rice. And of course, that tracks very closely our field production practices and our SOPs that we have with USDA.

What's really happening there is that our transparency with the industry and with CDFA is becoming greater. I would say that that's what's happening there. The transparency of what we're doing, in particular the molecules that we are expressing in our crop, are becoming more well known to the public. And I would say we're not having really very many negative impacts from that; we think it's a very positive process.

The group that we're working with in particular has been very willing to take a good deal of responsibility

on themselves for helping us create an identity preservation system. But they are also seeking to understand adventitious presence, tolerance levels, how does the FDA come into this picture. I would say that those are some very important things that they are trying to work around now. We haven't completely resolved our protocol with them.

So we look forward to again working with BIO trying to figure out the adventitious presence issue between APHIS and FDA. And we are not seeking to become deregulated with any of our products; we feel that we will have a long-term relationship with USDA under regulation, regardless of the safety of our molecule of interest.

MS. KOEHLER: Can I ask you what motivates you not to seek deregulation if you think your products are safe? I think that it would help us to articulate that to other people.

MS. ROBERTS: I think that we -- well, there are several things. I think that we feel it's very important for public perception that we are managing our crops safely, and that we feel that, as a partner, USDA is very good for us in that category.

For me, as a practitioner, as an agronomist, I think it also is a really great motivation for keeping our people in line. The Plant Protection Act in particular has been very helpful as an incentive, shall we say. And we

just don't want to lose that oversight, frankly.

And we think that there is a good deal of public trust in this particular area, and it's absolutely required for what we do.

MS. SMITH: Other questions? Okay. We really appreciate you coming in today.

MS. ROBERTS: Thank you.

MR. TURNER: Very helpful.

MS. SMITH: What we're going to do next is have the staff get together and do a debrief. And then we will, we can do that in plenty of time to break for lunch, or to the next session.

(Whereupon, at 10:15 a.m., the meeting in the above-entitled matter was adjourned.)

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REPORTER'S CERTIFICATE

CASE TITLE: VENTRIA BIOSCIENCE MEETING
HEARING DATE: February 25, 2004
LOCATION: College Park, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: February 25, 2004

Renee Miskell
Official Reporter
Heritage Reporting Corporation
Suite 600
1220 L Street, N. W.
Washington, D. C. 20005-4018